Sent: Friday, April 8, 2005 11:02 AM

To: NIEHS NICEATM Subject: Draize Testing

8 April 2005

Mr. William Stokes, D.V.M. Director NICEATM, NIEHS P.O. Box 12233, EC-17 Research Triangle Park, NC 27709

Dear Mr. Stokes,

In the January/February 2005 issue of the Humane Activist, The Humane Society of the United States (HSUS) newsletter, in the article, "Phasing Out the Draize," I learned that you were soliciting public comment on the panel's report in a Federal Register notice that was slated for mid-March.

I recommend that federal agencies immediately (1) begin accepting the alternative methods found to be useful; (2) move forward with recommended improvements in the alternative without delaying the acceptance of the tests' current forms; and (3) go beyond the current efforts by developing and validating non-animal methods to completely replace the use of the Draize test.

The scoring of eye and skin damage in the Draize test is highly subjective, and therefore, different laboratories—and even different tests within the same laboratory—often yield different results. In addition, rabbits' eyes are anatomically and physiologically different from and tend to have stronger reactions to chemicals than humans' eyes. According to R. Roggeband, "Eye Irritation Responses in Rabbit and Man After Single Applications of Equal Volumes of Undiluted Model Liquid Detergent Products," in *Food and Chemical Toxicology*, 38 (2000), he found that the Draize test "grossly overpredicted the effects that could be seen in the human eye." He also reveals that the test "does not reflect the eye irritation hazard for man." In contrast, he states in "Validity and Ethics of the Human 4-h Patch Test as an Alternative Method to Assess Acute Skin Irritation Potential," in *Contact Dermatitis*, 45 (2001), a clinical skin patch test conducted on human volunteers has been shown to produce skin-irritation data that are "inherently superior to that given by a surrogate model, such as the rabbit."

Sincerely,

Tina M. Bailey